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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,892

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Shigeru Hiramoto

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EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT

PAPER NUMBER

1661

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/22/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/501,892	Applicant(s) HIRAMOTO ET AL.	
	Examiner S. B. McCormick-Ewoldt	Art Unit 1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11-2-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of November 2, 2006 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected species, "animal proteins derived from milk" and "lactose" in the reply filed on February 7, 2006, is acknowledged.

With regard to Applicant's request to the election of species withdrawal since claims 15-21 are silent on the species, it is noted to Applicant that the species are clearly the same as in the species requirement. Therefore, the election of species is maintained and would equally apply to the method claims.

The requirement is still deemed proper and is therefore is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement on November 2, 2006 has been considered. An initialed copy is attached.

Claims Pending

Applicant has cancelled claims 1-14. Claims 15-21 are pending and are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The rejection is over the recitation “a food comprising 0.5% by mass or more” as amended in claim 15. The specification discloses “in food is generally about 0.5% to 10% by mass, and preferably 1.0% to 3.0% by mass” (see page 9, lines 12-15). Thus, an attempt to broaden the amount of a food “a food comprising 0.5% by mass or more” adds new matter. The specification does not mention a food comprising 0.5% by mass or more; thus, this limitation is deemed new matter.

Applicant is required to specifically point to support for the above newly recited limitation or to cancel the new matter in the reply to the Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-17 remain rejected under 35 U.S.C. 102(e) as being anticipated by Kim *et al.* (US 6,627,238) for reasons set forth in the previous Office action which are restated below. Applicant's arguments filed November 2, 2006 have been fully considered but they are not persuasive.

Kim *et al.* (US 6,627,238) expressly teach the well-known Maillard reaction, which is combining naturally occurring sugars and proteins and heated (i.e. browning) (column 1, lines 24-30). Kim discloses that lactose could be used as the sugar and casein, an animal protein derived from milk, as the protein. The browning composition of the sugar and protein is used in food products (column 2, lines 4-10). However, by consuming the food (i.e. browning reaction) one would be inherently inhibiting *Helicobacter pylori*. Therefore, the browning reaction of Kim *et al.* meets the limitations of claim 15 and thus anticipates the claimed invention.

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Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Applicant argues that Kim describes "the composition is coated onto the surface of the dough crust in an amount of about 0.008 to 0.02 gm/sq. cm" that the foods disclosed in Kim do not comprise the 0.5% by mass or more of a browning product. This is not found persuasive because the numerical values cannot be comparable. With regards to the Hirano reference in which Applicant disclosed that foods known to comprise a browning product actually comprise 31.3 ug/m (0.00313%). This has no relevance because there are literally hundreds of different types of foods that aren't disclosed that contain a browning product which would contain a higher percentage of browning product. For example, baked goods, cookies, candies, etc.

Therefore the rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kim *et al.* (US 6,627,238) in view of Kodama (US 6,828,298) for reasons set forth in the previous Office action which are restated below.

Kim *et al.* (US 6,627,238) discloses the well-known Maillard reaction, which is combining naturally occurring sugars and proteins and heated (i.e. browning) and can be used with an aqueous emulsion. Kim discloses that lactose could be used as the sugar and casein, an animal protein derived from milk, as the protein. The browning composition of the sugar and protein is used in food products (column 1, lines 24-30; column 2, lines 4-10).

Kim does not disclose wherein the product is used as an adhesion inhibitor for *Helicobacter pylori* or wherein the food is raw cow's milk or milk powder or skim milk powder or whey or evaporated milk or wherein the browning reaction is carried out at an absorbance at

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405 nm or wherein using the browning reaction of sugar and protein is used with an inhibitor of gastric-acid secretion or other substances capable of eradicating *Helicobacter pylori* such as a polyphenol or an antibiotic or an antibody against *Helicobacter pylori* or a polysaccharide or glycoprotein capable of binding to a *Helicobacter pylori* urease or wherein a pharmaceutical composition is used to treat diseases associated with *Helicobacter pylori* or wherein a method for inhibiting *Helicobacter pylori* by administering an effective amount of the product of the browning reaction between sugar and protein.

Kodama (US 6,828,298) discloses a glycoprotein capable of binding to *Helicobacter pylori* urease. Glycoproteins contained in bovine milk include lactoferrin (i.e. animal protein derived from milk). The glycoprotein is used as an inhibitor of *Helicobacter pylori* colonization in the stomach and is useful for treating diseases associated with *Helicobacter pylori*. Kodama also discloses a food which treats diseases caused by or associated with *Helicobacter pylori* in mammals, including humans when consumed in an effective amount. Glycoprotein can be added to foods for special health use or special dietary use. Foods for specified health uses include milk and dairy products. Kodama also disclose that a pharmaceutical composition may further comprise an inhibitor of gastric acid secretion. The combination of glycoprotein and the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori* from the stomach. (column 2, lines 55-65; column 3, lines 1-11, 56-57; column 5, lines 27-67; column 6, lines 23-26, 66-67; column 7, 1-4).

One of ordinary skill in the art would have been motivated to use the product of the browning reaction between sugar and protein for inhibiting *Helicobacter pylori* adhesion inhibitor would be inherent to the food item. By adding the glycoprotein and gastric acid secretion inhibitor composition of Kodama with a food product, one would gain added benefits from the composition of Kodama. Although none of the references disclose the absorbance at 405 nm, one of skilled in the art would optimize that particular parameter. It was clear from Kim that the well-known Maillard reaction (i.e. the combining of naturally occurring sugars and proteins and heated (i.e. browning)) is routinely in food products. It was further clear from Kodama that a glycoprotein is capable of binding to *Helicobacter pylori* urease and is used as an inhibitor of *Helicobacter pylori* colonization in the stomach and is useful for treating diseases associated with *Helicobacter pylori* and be incorporated into a food product. Therefore, one of

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ordinary skill in the art would have had a reasonable expectation that by combining the browning reaction between sugar and protein and the glycoprotein and gastric acid secretion inhibitor composition with a food product, one would gain added benefits for *Helicobacter pylori* adhesion inhibitor.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered but are not deemed persuasive.

Applicant argues it is common knowledge that a browning product and a glycoprotein are very different, not only in chemical structure, but also in biological activity and a person skilled in the art would not have been motivated to use a browning product for inhibiting *Helicobacter pylori* adhesion. This is not found persuasive because glycoproteins are contained in bovine milk include lactoferrin, a protein derived from animal milk (col. 3, lines 56-57; and specification page 4, lines 21-23). Therefore, the glycoproteins would be incorporated into any of the food product as disclosed a Kodama (col. 5, lines 27-50). Additionally, glycoproteins do not lose its physiological activity due to heat and can be readily recovered and purified from its starting material so would be advantageous with respect to formulation into a food (col. 4, lines 51-57).

Applicant argues the cited references make no mention of treating specific diseases by the present method and does not disclose or suggest administering the recited composition to a patient have such disease, as recited in claim 20. This is not found persuasive because as disclosed in Kodama provides a food which treats diseases caused by or associated with *Helicobacter pylori* (col. 3, lines 7-11) and further comprise an inhibitor of gastric acid secretion (column 6, lines 66-67; column 7, 1-4). Additionally, there is no specific disease associated with *Helicobacter pylori* as claimed in claim 20.

Applicant argues it is not apparent where there is motivation to combine these very different references nor would such combination lead to the present invention. This is not found persuasive as discussed *supra*, Kim discloses the well-known Maillard reaction (i.e. the

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combining of naturally occurring sugars and proteins and heated (i.e. browning)) is routinely in food products and by adding the glycoprotein and gastric acid secretion inhibitor composition of Kodama with a food product, one would gain added benefits from the composition of Kodama. It was further clear from Kodama that a glycoprotein is capable of binding to *Helicobacter pylori* urease and is used as an inhibitor of *Helicobacter pylori* colonization in the stomach and is useful for treating diseases associated with *Helicobacter pylori* and be incorporated into a food product. Therefore, one of ordinary skill in the art would have had a reasonable expectation that by combining the browning reaction between sugar and protein and the glycoprotein and gastric acid secretion inhibitor composition with a food product, one would gain added benefits for *Helicobacter pylori* adhesion inhibitor.

In response to **Applicant's argument** that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore the rejection is proper and is maintained.

Summary

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme



CHRISTOPHER R. TATE
PRIMARY EXAMINER